

use of all medicines. Campaigns to inform patients about self education would be to the public benefit.

Good teamwork is essential

Encouraging the public to seek advice from the community pharmacist may lead to a greater proportion of visits to doctors resulting from referrals from the pharmacist, perhaps through formal referral forms. The change in status of prescription only medicines to pharmacy sale may also result in general practitioners referring patients to the pharmacist to purchase an over the counter medicine. The opportunities for team-working between the two professions will grow. One way to encourage good teamwork is for general practitioners, pharmacists, and others to collaborate in the development of clinical treatment guidelines for specific conditions—for example, dyspepsia.¹⁷ The process of developing such guidelines has resulted in better understanding of different levels of professional care and produced guidelines that were welcomed by community pharmacists. Other initiatives to help integrate community pharmacists to achieve a recognised place in the primary health care team must be formally pursued.

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North of England evidence based guidelines development project: methods of guideline development

Martin Eccles, Zoe Clapp, Jeremy Grimshaw, Philip C Adams, Bernard Higgins, Ian Purves, Ian Russell

This is the first of three articles on developing evidence based guidelines for the primary care management of asthma and angina in adults

*The evidence on which these guidelines are based appears in full in the BMJ's world wide web page:
<http://www.bmj.com/bmj/>*

There is increasing interest in clinical guidelines in Britain. With this interest has come increasing awareness of the methodological issues in the development of valid guidelines.¹⁻³ Practice guidelines are considered valid if "when followed, they lead to the health gains and costs predicted for them."⁴ When appropriately disseminated and implemented, valid guidelines can lead to changes in clinical practice and improvements in patient outcome.⁴⁻⁷ Conversely, the dissemination and implementation of invalid guidelines may lead to wasteful use of resources on ineffective interventions or, worse, deterioration in patients' health.

Validity has been related to three principal factors in guideline development—namely, the composition of the guideline development panel and its processes; the identification and synthesis of evidence; and the method of guideline construction.⁸ Though these factors have been discussed at theoretical⁹ and more practical levels,⁸ there have been few attempts to put them into practice in Britain. In this series of three papers we describe the methods used to develop evidence based guidelines for the primary care management of two common chronic conditions—namely, asthma in adults and stable angina—and summary versions of the two guidelines that resulted.^{9,10}

Guideline development groups

The guideline development groups were composed of relevant health care professionals and patients; a specialist resource (a consultant chest physician for asthma and a consultant cardiologist for stable angina) and an experienced small group leader; and members of the research team. All group members were offered reimbursement of travelling expenses, and general practitioners and practice nurses were offered reimbursement of any locum expenses.

Evidence review and synthesis

SEARCH STRATEGY

The search was carried out with Medline and covered the 10 years 1985-94. This was a pragmatic decision influenced by the volume of papers and the time and resources available. All searches were confined to studies of human adults written in English. For both topics we conducted medical subject heading and free text searches using the terms meta-analysis, randomised controlled trial, review, cohort study, and case-control study. For asthma we also sought the terms asthma, peak expiratory flow rate, obstructive lung disease, forced expiratory volume, and paroxysmal dyspnoea; for stable angina we sought the terms coronary disease and angina pectoris. Additional specific Medline searches were carried out by using the following terms: decision making, theophylline, terbutaline, antihistamine, isosorbide, myocardial infarction plus secondary prevention, and buccal.

The BIDS (Bath Information and Data Services, Institute for Scientific Information, University of Bath) electronic database was also searched (by using the terms "asthma+management" and "angina+management"). In addition, references were identified from two other sources. Firstly, if there was no recent evidence in a clinically important topic the specialist resource was asked to identify from personal knowledge key articles published before 1985. Secondly, the reference lists of non-systematic reviews were checked. We did not attempt to access the grey literature, nor did we identify letters in response to original articles.

ASSESSING THE LITERATURE

The sets of references generated by the searches were sifted for relevance to the clinical topic of the guidelines. The initial sifting was done by a clinically qualified health services researcher (ME) on the basis

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BMJ 1996;312:760-2

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of article titles. Irrelevant articles were removed. If there was doubt about the relevance of an article it was retained for the next round of sifting, which identified references needing detailed assessment. This was performed by the specialist resource on the basis of title and abstract (when these were available). The identified papers were reviewed against explicit methodological criteria informed by several sources.¹¹⁻¹⁸ Owing to the volume of literature, this task was extended beyond the single specialist resource in each group by inviting group members to review discrete areas on behalf of the group. Reviewers were provided with explicit written instructions to ensure consistency. Some studies which passed methodological sifting still had flaws—for example, negative studies without a power calculation. This was made explicit within the description of the study or within accompanying comments.

SYNTHESISING THE EVIDENCE

Once individual papers had been checked for methodological rigour and clinical relevance they were categorised according to study design. The three categories shown in box 1 were adapted from those of the Canadian Task Force.¹⁹ In the early meetings tables summarising the evidence were circulated to group members beforehand. Initially the evidence was discussed and synthesised into recommendations by the group within meetings. In later meetings this process was conducted by the reviewer and the research team outside group meetings and provisional recommendations were made. These were circulated for comment as a postal exercise to ensure time for finalising recommendations within the meetings.

Box 1—Categories of evidence

- (I) Based on well designed randomised controlled trials, meta-analyses, or systematic reviews
- (II) Based on well designed cohort or case-control studies
- (III) Based on uncontrolled studies or consensus

The evidence was synthesised by qualitative methods. These entailed summarising the content of identified papers into brief statements that the group thought accurately reflected relevant evidence. Quantitative (meta-analysis) techniques were not used, as we were dealing with studies other than randomised controlled trials. Recommendations were derived by informal consensus methods. Though interpreting evidence inevitably involves value judgments, by making this process explicit we made the scientific basis of these judgments as clear as possible. Box 2 shows the relation between strength of recommendation and category of evidence. The strength of recommendation was shown as A, B, or C after each recommendation.

TOPICS WITHOUT EVIDENCE

Consensus methods were used to develop recommendations for topics without evidence. The asthma group agreed to refer to the consensus recom-

Box 2—Strength of recommendation

- (A) Directly based on category I evidence
- (B) Directly based on category II evidence or extrapolated recommendation from category I evidence
- (C) Directly based on category III evidence or extrapolated recommendation from category I or II evidence

Box 3—Implications for practice

- The guidelines were developed by using methods to maximise their validity: identification of evidence by systematic review, development by a multi-disciplinary group, and the use of explicit links between evidence and recommendations
- The explicit nature of the guideline development process allows potential users to critically appraise the validity of the guidelines and make an informed judgment about whether to adopt them in their clinical practice
- The guidelines propose principles of good practice; these could be modified locally, based on the evidence and strength of recommendation and taking into account local preferences and resources

mendations of British Thoracic Society asthma guidelines.²⁰ In the absence of an equivalent document the angina group drew up its own consensus recommendations.

External review of guidelines

External reviewers were chosen to reflect three groups: potential users of the guidelines; content topic experts; and guideline methodologists. Though their comments influenced the style and content of the guidelines, these remained the responsibility of the development group.

Scheduled review of guidelines

The guidelines should be reviewed for their content and evidence base no later than three years after completion.

Implications for practice

Box 3 shows the implications for practice.

We thank Liz Wood for administrative support. The views expressed are ours and not necessarily those of the funding bodies.

Funding: The north of England evidence based guidelines development project was funded by the research and development directorate of the former Northern Regional Health Authority, now the Northern and Yorkshire Regional Health Authority. The health services research unit is funded by the chief scientist's office of the Scottish Office Home and Health Department.

Conflict of interest: PCA frequently receives fees from pharmaceutical companies for lecturing on coronary artery disease.

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(Accepted 9 December 1995)

North of England evidence based guidelines development project: summary version of evidence based guideline for the primary care management of asthma in adults

North of England Asthma Guideline Development Group

This is the second of three articles on developing evidence based guidelines for the primary care management of asthma and angina in adults

The evidence on which these guidelines are based appears in full on the BMJ's world wide web page: <http://www.bmj.com/bmj/>

The aim of this guideline is to provide recommendations (evidence based when possible) to guide primary health care professionals in their management of adult patients with asthma. It is a summary version of the full guideline,¹ to which reference should be made for clarification or further information. The development group assumes that health care professionals will use general medical knowledge and clinical judgment in applying the general principles and specific recommendations in this document to the management of individual patients. Recommendations may not be appropriate for use in all circumstances. Decisions to adopt any particular recommendation must be made by the practitioner in the light of available resources and circumstances presented by individual patients. Throughout this guideline categories of evidence (cited as I, II, and III) and the strength of recommendations (A, B, or C) are as described in the first article in the series.²

Scope of guideline

Aspects covered by the guideline are the use of peak flow measurement in diagnosis and management, drug treatment, non-drug treatment, and referral. All recommendations are for primary health care professionals and apply to adult patients attending general practice with asthma.

Aims of treatment

Comment—British Thoracic Society guidelines state the aims of treatment as patients having the least possible symptoms; the least possible need for relieving bronchodilators; the least possible limitation of activity; the least possible circadian variation in peak flow; the least possible adverse effects from medicine; and the best peak flow possible.³ It is preferable to adjust treatment to cover exposure to day to day triggers such as exercise and cold air because avoidance imposes inappropriate restrictions on lifestyle. Specific comments about adjusting the dosages of drugs are made within the relevant sections on drug treatment.

Peak flow: diagnosis and management

RECOMMENDATIONS

- Peak flow variability can be used to help in the diagnosis of recurrent wheeze (B)
- The routine home use of peak flow meters for self management is not mandatory (A)
- Morning "dipping" should be regarded as a sign of transient poor control (B)

- Peak flow monitoring can be useful to assess patients and inform management (C).

Peak flow variability can be used to help in the diagnosis of recurrent wheeze (II).^{4,5} Though monitoring peak flow can be useful to assess patients and inform management (III), the routine home use of peak flow meters does not alter patient outcomes (I).⁶ Morning "dipping" of peak flow values reflects transient rather than long term poor control (II).⁷ Additionally, in acute situations peak flow can be used to predict outcome (III).⁸

Drugs used in the treatment of asthma

Comment—All recommendations for treatment apply only in the absence of recognised contraindications, side effects, or interactions as documented in the *British National Formulary*.⁹

Compliance

RECOMMENDATION

- Compliance with treatment is important and should be checked regularly, especially if symptom control is poor or treatment is about to be increased (C).

Sequencing of treatment

Comment—There is little evidence to answer the important clinical questions of appropriate sequencing of treatment and the relative places of various agents in drug management. Drugs are therefore considered in the order of presentation in the *British National Formulary*.⁹ A suggested sequencing is provided after consideration of the drugs.

Short acting β_2 agonists

RECOMMENDATIONS

- Short acting β_2 agonists are effective bronchodilators (A)
- They should be used on an as required basis to relieve symptoms (C)
- They should be used before exercise in patients who have exercise induced bronchospasm (A).

Though short acting β_2 agonists are effective as judged by an increase in peak expiratory flow (I),¹⁰ there is conflicting evidence on the issue of as required versus regular dosage (I).^{11,12} For patients who need four daily doses of a short acting β_2 agonist the two studies identified give contradictory findings. Salbutamol is effective for exercise induced bronchospasm and is more effective than sodium cromoglycate (I).¹³

North of England Asthma Guideline Development Group

Members of the guideline development and technical advisory groups are listed at the end of this report.

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BMJ 1996;312:762-6